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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/777,566

02/05/2001

Jay M. Short

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EXAMINER

RAMIREZ, DELIA M

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/777,566

Applicant(s)

SHORT ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 16-43 and 45-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-27, 29-32, 34-43, 45-76 is/are rejected.
- 7) ☒ Claim(s) 28 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/30/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Claims 1-13, 16-43, 45-76 are pending.

Applicant's amendment of claims 2, 10-12, 16, 21-23, 35-43, 46, cancellation of claim 44, addition of claims 47-76, submission of references by Wyss et al., Wodzinski et al., Berka et al, Kerovuo et al., and four GenBank entries corresponding to phytases, in a communication filed on 11/23/2004 are acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 8/30/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

2. The specification was objected to for the following reasons. The disclosure (paragraph 109 of U.S. Publication No. 2001/0055788) indicates that the polynucleotide encoding SEQ ID NO: 2 contains an open reading frame encoding a protein of 432 amino acids. SEQ ID NO: 2 according to the sequence listing contains 440 amino acids. SEQ ID NO: 1 was found to encode all 440 amino acids of SEQ ID NO: 2. While it appears that the polypeptide of SEQ ID NO: 2 comprises a His tag at the C-terminus, this tag is 6 amino acids long. Thus, even if one does not consider the His tag, the remaining polypeptide would have 434 amino acids and not 432 amino acids as asserted.

3. Applicants argue that the polypeptide of SEQ ID NO: 2 has 440 amino acids because it contains the phytase, which is 432 amino acids long, a histidine tag of 6 amino acids, and a linker between the

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phytase and the histidine tag which is 2 amino acids long. Therefore, even if the polypeptide of SEQ ID NO: 2 contains 440, the polynucleotide encoding the polypeptide of SEQ ID NO: 2 still contains an open reading frame encoding a protein of 432 amino acids. Applicants submit a reference by Wyss et al. which teaches the histidine tag with the linker. Applicant's arguments have been fully considered. Since the phytase portion of the polypeptide of SEQ ID NO: 2 corresponds to amino acids 1-432, and the additional amino acids appear to be a linker joining the histidine tag with the phytase, the instant objection is hereby withdrawn.

Claim Objections

4. Claim 46 is objected to due to the recitation of "wherein the exogenous nucleic acid comprising a nucleic acid (i) comprising a nucleotide sequence, (ii) comprising a nucleotide sequence., (iii) encoding..., (iv) encoding....., or (v) comprising...". For clarity and consistency, the claim it should be amended to recite "wherein the exogenous nucleic acid (i) comprises a nucleotide sequence, (ii) comprises a nucleotide sequence., (iii) encodes..., (iv) encodes....., or (v) comprises...". Appropriate correction is required.

5. Claims 55-56 are objected to due to the recitation of "wherein the nucleic acid further comprises a sequence encoding a signal peptide or a transit peptide, a promoter....a targeting sequence or a termination sequence and optionally the signal peptide comprises....., or optionally the signal peptide is a secretory....". For clarity and consistency, the claims should be amended to recite "wherein the nucleic acid further comprises (i) a sequence encoding a signal peptide or a transit peptide, (ii) a promoter sequence, (iii) a secretory.....or (vi) a termination sequence; and optionally the signal peptide is a secretory signal peptide or comprises a pathogenic.....". In the alternative, it is suggested that limitations regarding the signal peptide be placed in a dependent claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 21-22, 34 remain rejected and claims 16-17, 20, 35-43, 46-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection of claims 16-17, 20, 35-43, 46-76 is necessitated by amendment.

8. Claims 16, 34, 57-58 (claims 17, 20-22 dependent thereof) are indefinite in the recitation of “wherein the phytase activity comprises hydrolyzing inorganic phosphate from phytate or the reverse reaction” or “wherein the phytase activity comprises hydrolyzing inorganic phosphate” for the following reasons. As previously indicated, the art recognizes hydrolysis of inorganic phosphate from phytate as the enzymatic activity of a phytase and not the reverse reaction. Therefore, the terms as written are not further limiting the phytase activity of claims 16, 47-50. See discussion in previous Office Action. It is suggested that if Applicant’s intended subject matter is an expression system for making a polypeptide having enzymatic activity, wherein said enzymatic activity comprises hydrolyzing inorganic phosphate from phytate or the reverse reaction, or a vector comprising a nucleic acid encoding a polypeptide having enzymatic activity, wherein said enzymatic activity comprises hydrolyzing inorganic phosphate from phytate or the reverse reaction, claims 16 and 47-50 should be amended accordingly. Dependent claims 34 and 57-58 can be then amended to recite the limitation “wherein the enzymatic activity comprises hydrolyzing inorganic phosphate from phytate”. It is noted that if the suggested amendments are made, claims which ultimately depend upon claims 16, 47-50 and recite the term “phytase”, “phytase activity”, “phytase protein” should be amended to maintain the proper antecedent basis. Correction is required.

9. Claims 35-43 and 46 are indefinite in the recitation of “sequence that is the complement of...” because it is unclear which complement is being referred to. Fragments of any size which are

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complementary to the nucleotide sequences recited can be considered as “complements”. As indicated previously, Applicants have not defined the term as it relates to size in the specification. It was suggested previously to amend the term so that it recites “complete complement”. Correction is required.

10. Claim 46 is indefinite in the recitation of “a method for making a phytase in a cellwherein the exogenous nucleic acid encoding the phytase...(v) comprises a sequence that is the complement of ...” since a nucleic acid comprising a sequence which is the complement of what is recited does not encode the phytase. For examination purposes, no patentable weight will be given to item (v). Correction is required.

11. Claims 47-50, 61-62, 71-76 (claims 51-60, 63-70 dependent thereof) are indefinite in the recitation of “at least about” because it renders the claims vague and confusing. The use of this language is contradictory because the term “about” can be interpreted as “less than” whereas the term “at least” is synonym of “no less than”. For examination purposes, it will be assumed that the term reads “at least”. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. New claims 47-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection, which was applied to claims 2, 10-13, 16-17, 20-44, and 46, is now applied to newly added claims 47-70 for the reasons of record and those set forth below.

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14. Applicants argue that the claimed invention is sufficiently described in the specification such that one of skill in the art would be able to recognize that Applicants were in possession of the claimed invention at the time of filing. Applicants refer to *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) and *Enzo Biochem. Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002) in support of the argument that the claimed invention is adequately described since structure and function is being recited in the claims. Applicants submit that the claims expressly define what is a conservative substitution within the scope of the invention.

Applicants further argue that it was not necessary to know the correlation between structure and function of phytases to be in possession of the claimed invention and refer to Dr. Short's declaration, previously submitted, where it is stated that one of ordinary skill in the art would be able to make and screen for nucleic acids encoding the recited polypeptides. Applicants refer to an alignment of the polypeptide of SEQ ID NO: 2 and several phytases known in the art in support of the argument that a structure function information for phytases was available to one of skill in the art. In particular, Applicants indicate that there are conserved residues and a conserved phytase active site. Applicants also submit that the claims have been amended to limit the extent of amino acid substitution to "50% sequence identity to SEQ ID NO: 2".

15. Applicant's arguments have been fully considered but are not deemed persuasive to avoid the rejection of new claims 47-70. The Examiner acknowledges the teachings of the specification, the limitations recited in regard to function and structure, the alignment provided, and Dr. Short's declaration. However, the Examiner disagrees with Applicant's contention that the claims are adequately described by the specification. Claims 47-70 are directed in part to a vector comprising a genus of nucleic acids, wherein said nucleic acids (1) encode a genus of phytases, or enzymatically active fragments thereof, wherein the phytases comprise the amino acid sequence of SEQ ID NO: 2, or amino acids 1-432 of SEQ ID NO: 2, with any number of conservative substitutions, and wherein the phytase is at least 50%

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sequence identical to SEQ ID NO: 2, (2) cells comprising a genus of nucleic acids as described in (1) above, (3) expression systems for making the polypeptides encoded by the genus nucleic acids of (1) as described above, and (4) a method of making a genus of phytases, or enzymatically active fragments thereof, encoded by the genus of nucleic acids described in (1). While it is agreed that the claims are now limited in regard to the amount of structural variation such that the phytase recited is at least 50% sequence identical to SEQ ID NO: 2, it is noted that the structural variation recited is still extremely large. The polypeptide of SEQ ID NO: 2 is 440 amino acids long. Thus, the genus of phytases recited encompasses phytases having SEQ ID NO: 2 and up to 220 conservative amino acid substitutions, wherein each of these substitutions can in turn be made with several different amino acids, as recited in the claims. For example, if only one amino acid substitution is made in the polypeptide of SEQ ID NO: 2 (99.8% sequence identity to SEQ ID NO: 2; $99.8\% = 439 \times 100 / 440$) where the amino acid to be substituted is Ala, there are up to 3 species which can be made since the Ala residue can be replaced with either Val, Leu or Ile. The structural features recited, i.e. encoding a phytase which results from any number of conservative substitutions, wherein the phytase has at least 50% sequence identity to the polypeptide of SEQ ID NO: 2, does not constitute a substantial portion of the genus as the remainder of any nucleic acid encoding a phytase comprising said structural elements is completely undefined and the specification does not define the remaining structural features for members of the genus to be selected. The Examiner acknowledges the alignment provided and the fact that the structural variation has to be the result of conservative substitutions, however it is noted that while there are some conserved amino acids among the phytases in the alignment and a short motif in the active site, there is no indication in the art or the specification which discloses (1) these few conserved amino acids as solely responsible for phytase activity, and (2) the variable amino acids not to be related to phytase activity, such that conservative substitution of these variable amino acids would not result in changes in activity. Furthermore, the claims do not recite any limitation in regard to where the conservative amino acid substitutions are made in the

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polypeptide of SEQ ID NO: 2. Also, it is noted that one of skill in the art would not expect any conservative substitution to have no effect on enzymatic activity. In fact, the art, as evidenced by the teachings of Witkowski et al., previously cited, clearly indicates that even one single conservative substitution can have a major impact in enzymatic activity. Therefore, contrary to Applicant's assertions, there is no disclosed structure/function correlation for phytases such that one of skill in the art would know which amino acids in the polypeptide of SEQ ID NO: 2 can be conservatively substituted, and which amino acids to substitute with, such that the enormous number of nucleic acids encoding the recited phytases recited are adequately described.

16. New claims 47-76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding the polypeptide of SEQ ID NO: 2, a nucleic acid encoding amino acids 1-432 of SEQ ID NO: 2, a nucleic acid encoding an enzymatically active fragment of the polypeptide of SEQ ID NO: 2, a vector and a host cell comprising said nucleic acids, as well as a method of recombinantly producing the polypeptide of SEQ ID NO: 2, a polypeptide comprising amino acids 1-432 of SEQ ID NO: 2, or an enzymatically active fragment of the polypeptide of SEQ ID NO: 2 in a cell, does not reasonably provide enablement for (1) nucleic acids which encode phytases, or enzymatically fragments thereof, wherein the phytases have at least 50% sequence identity to SEQ ID NO: 2, wherein said phytases comprise (i) the amino acid sequence of SEQ ID NO: 2, or (ii) amino acids 1-432 of SEQ ID NO: 2, and wherein the phytase amino acid sequence has any number of conservative substitutions, (2) cells comprising the nucleic acids as described in (1) above, (3) expression systems for making polypeptides encoded by the nucleic acids of (1) as described above, or (4) methods of making phytases encoded by the nucleic acids described in (1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection, which was applied to claims 2, 10-13,

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16-17, 20-44, and 46, is now applied to newly added claims 47-70 for the reasons of record and those set forth below.

17. Applicants argue that the Examiner has not met her initial burden to establish a reasonable basis to question the enablement provided. In particular, Applicants submit that Broun et al., Witkowski et al. and Seffernick et al. appear to support the argument that most changes in an enzyme's amino acid sequence are not important in determining or changing its catalytic specificity. Therefore, Applicants submit that these references support the idea that most changes in an enzyme's amino acid sequence will result in little or no effect on its specificity or activity. Applicants also submit that the Examiner did not sufficiently consider Dr. Short's declaration and that the arguments and statements made by Dr. Short are sufficient to rebut any possible prima facie case of lack of enablement. Applicants argue that the specification provides phytase activity assays, and which amino acid substitutions can be made to make a variant phytase within the scope of the invention. Applicants also indicate that it was not necessary for the specification to disclose a correlation between structure and function of phytases to enable the claimed invention. Applicants refer to an alignment of the polypeptide of SEQ ID NO: 2 against several phytases in support of the argument that a structure/function correlation was known in the art at the time of filing. According to Applicants, the alignment discloses conserved amino acid residues and a motif in the active site. Applicants also submit that the claimed genus has been amended to further limit the sequence to at least about 50% sequence identity to SEQ ID NO: 2.

18. Applicant's arguments have been fully considered but are not deemed persuasive to avoid the rejection of new claims 47-76. The Examiner acknowledges (1) the structural limitation recited wherein the amount of structural variation is limited to 50% sequence identity to SEQ ID NO: 2, (2) teachings of the specification, (3) Dr. Short's declaration, and (4) alignment provided. However the Examiner disagrees with Applicant's contention that the claimed invention is enabled by the teachings of the specification. In regard to the references by Broun et al., Witkowski et al. and Seffernick et al, it is noted

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that while it is agreed that one of skill in the art would certainly expect changes in the catalytic site of an enzyme to have an effect on activity and/or specificity, it is noted that neither one of these references teach that any amino acid change in the non-catalytic sites would not have any effect on specificity or activity. In fact, one of skill in the art would not expect any amino acid change in the non-catalytic sites to have no effect whatsoever in an enzyme since it is well known in the art that amino acid changes in non-catalytic sites may result in changes in the 3D structure of a protein such that folding would change to the extent that enzymatic activity/specificity is affected. Furthermore, while the catalytic site of an enzyme is essential for enzymatic activity, it is noted that those amino acids which are not part of the catalytic site must have a function associated to an enzyme's activity and/or substrate specificity. This is evidenced by the fact that there is diversity in substrate and/or activity within a family of enzymes.

In regard to the alignment presented, it is noted that the Examiner disagrees with Applicant's contention that the prior art teaches a phytase structure/function correlation. As indicated above, there is no teaching which suggest that (1) the conserved amino acids are all that is required in a polypeptide to display phytase activity, (2) the variable amino acids are not related to phytase activity such that any conservative amino acid substitution would have no effect on this activity. Also, as indicated above, there is no limitation in the claims in regard to where the conservative amino acid substitutions can be made in the polypeptide of SEQ ID NO: 2. Therefore, the genus encompasses not only species where the conservative substitutions are made within the variable regions of the polypeptide of SEQ ID NO: 2. Furthermore, even if one were to argue that the conservative substitutions are to be made only in the non-catalytic regions, there is no teaching in the specification or the art which provides the amino acids to substitute with.

The Examiner respectfully disagrees with the notion that Dr. Short's declaration has not been sufficiently considered or that such declaration is sufficient to rebut any possible prima facie case of lack of enablement. As previously indicated, while the Examiner agrees that a phytase activity assay is well

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known in the art, and one could make the numerous species encompassed by the claims using well known molecular biology techniques, the number of species encompassed by the claims is extremely large.

Therefore, while testing a reasonable number of species would not constitute undue experimentation, in view of the fact that the genus of nucleic acids required is extremely large and the specification fails to disclose a structure/function correlation sufficient to allow one of skill in the art to select a reasonable number of species most likely to encode the recited phytases for testing, it would require undue experimentation to enable the full scope of the claims.

Double Patenting

19. Applicant is advised that should claim 59 be found allowable, claim 60 will be objected to under 37 CFR 1.75 as being an identical duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

20. Claims 1-13, 16-27, 29-32, 34-43, 45-46 remain provisionally rejected and new claims 47-66, 68-69, 71-76 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 87 and 91-94 of copending Application No. 10/430356.

21. Applicants note that claims 45-46, 52-53, 73, 87, 91, 95-123 are currently pending in application No. 10/430356. Also, Applicants indicate that they wish to hold this issue in abeyance until the instant claims are found allowable.

22. This rejection has been discussed at length in the previous Office Action. It is noted however that in view of the cancellation of claims 1-44 and amendment of claim 87 in copending Application No. 10/430356, the double patenting rejection previously applied over claims 1-15, 17-26 and 91-94 of copending Application No. 10/430356 is now made over claims 87 and 91-94 of copending Application

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No. 10/430356. It is noted that according to PTO records, claims 45-87 and 91-123 are still pending in copending application No. 10/430356. Claims 87 and 95-123 of copending application No. 10/430356 are now under consideration. Claims 45-86, 91-94 of copending Application No. 10/430356 have been withdrawn from consideration. It is noted that amended claim 87 of copending application No. 10/430356 is directed to a polynucleotide encoding a phytase wherein the phytase is at least 98% sequence identical to the polypeptide of SEQ ID NO: 2. Therefore, claims 1-12, 16-27, 34-43, 45, 47-65, 71-76 of the instant application, which are directed in part to vectors, expression systems, or host cells comprising a polynucleotide encoding a polypeptide having amino acid residues 1-432 of SEQ ID NO: 2, would be obvious over the polynucleotide of claim 87 for the reasons of record and also in view of the fact that (1) a polynucleotide encoding amino acid residues 1-432 of SEQ ID NO: 2 (440 amino acids long) is a preferred embodiment of the invention claimed in copending application No. 10/430356, and (2) a polypeptide comprising just amino acids 1-432 of SEQ ID NO: 2 would be at least 98% sequence identical to a polypeptide having SEQ ID NO: 2 ($98\% = 432 \times 100 / 440$). Claims 13, 29-32, 46, 66, 68-70 of the instant application are directed in part to a method of producing a phytase in a cell by culturing the cell under conditions which result in expression of a polynucleotide encoding a phytase having at least amino acids 1-432 of SEQ ID NO: 2. Since (1) claims 91-94 of copending Application No. 10/430356 are directed in part to a method of recombinantly making a phytase by introducing a nucleic acid into a plant cell via a vector, electroporation, microinjection or particle bombardment, wherein the nucleic acid encodes a phytase at least 98% sequence identical to the polypeptide of SEQ ID NO: 2, (2) a polypeptide having amino acids 1-432 of SEQ ID NO: 2 would be at least 98% sequence identical to the polypeptide of SEQ ID NO: 2 (440 amino acids long), and (3) a method to produce a phytase by culturing a cell capable of expressing a polynucleotide encoding a polypeptide having amino acids 1-432 is a preferred embodiment of the invention claimed in copending application No. 10/430356, then claims 91-94 of

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copending application No. 10/430356 would render claims 13, 29-32, 46, 66, 68-70 of the instant application obvious.

23. In view of the fact that no terminal disclaimer has been filed and no arguments have been presented pointing out disagreements with the Examiner's contentions, the obviousness-type double patenting rejection is maintained.

Allowable Subject Matter

24. Claims 28 and 33 appear to be allowable over the prior art of record but are objected to since they depend upon a rejected base claim.

Conclusion

25. No claim is in condition for allowance.

26. Applicant's amendment of claims 2, 10-12, 16, 21-23, 35-43, 46 and addition of claims 47-76 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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27. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (571) 273-8300. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

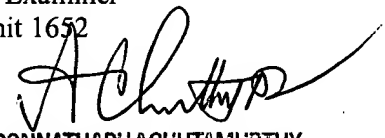
28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

DR
February 18, 2005

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1300